

Please rewrite claim 17 as follows:

17(twice amended). A method for the treatment of pain associated with periodontal scaling, comprising administering an effective amount of a pharmaceutical composition according to claim 1 to a patient in need of pain relief during periodontal scaling.

Remarks

I. Status of the Claims and Application

The above-captioned application represents U.S. national phase of international application PCT/SE97/00566. At the time of entry into the United States, the application had a total of 18 claims. In a Preliminary Amendment filed by Applicants on May 21, 1998, claims 13-16 were deleted and claims 3-5, 8-10, 12, 17, and 18 were amended. As described above, further amendments have been made herein to claims 1, 5-7, 8, 12, and 17. The claims presently pending in the application are 1-12, 17, and 18.

II. The Amendments

The specification has been amended on page 11 to make a minor correction in the designation of an international application. This was done in accordance with the suggestion of the examiner appearing on page 2 of the present Office Action.

Claim 1 was amended to delete several phrases that the examiner found objectionable. Step (ii) was also amended to indicate that at least one surfactant present in compositions must have thermoreversible gelling properties. Support for this amendment may be found on page 4 of the specification, lines 4-8. Claim 1 was also amended to indicate that compositions are in the form of an emulsion or microemulsion and have thermoreversible gelling properties such that they become more viscous when introduced onto a mucous membrane of a patient. Support for these amendments may be found on page 1 of the specification, lines 5-7, page 3, lines 4-6, and page 4, lines 19-23.

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Claims 5–7 were amended to replace the phrase “the active ingredient” with the phrase “said one or more local anaesthetics.” This amendment was made to overcome the examiner’s objection that the deleted phrase did not have proper antecedent basis.

Claims 8 and 12 were amended to correct a minor grammatical error and to replace trademarks with generic terminology.

Finally, claim 17 was amended to indicate that pharmaceutical compositions must be given in an effective amount. This was done to eliminate inoperative embodiments that clearly were not intended to be part of the claim and in response to the Examiner’s comment on page 2 of the Office Action, 5th line from the bottom.

None of the amendments discussed above add new matter to the application, and their entry is therefore respectfully requested.

The Rejections

I. Rejection of Claims Under 35 U.S.C. § 112, Second Paragraph

Pages 2 and 3 of the Office Action recite several rejections under 35 U.S.C. § 112, second paragraph. Claim 1 is rejected based upon allegedly indefinite terms present in paragraphs (i)–(iii). The claim has been amended herein to eliminate each phrase that the examiner found to be objectionable, thereby obviating the rejection.

Claims 8–10 and 12 were rejected based upon a minor grammatical error in which the word “one” had inadvertently been placed after the word “of” rather than before it. Applicants have amended claim 8 to correct this problem. It is believed that the remaining claims, i.e., 9, 10, and 12, did not have this error, and it is respectfully requested that the examiner verify that this is correct.

It is believed that all of the remaining rejections under §112 have also been overcome by the amendments set forth above. Specifically, claims 5–7 were amended to introduce terminology

that clearly has antecedent basis; claim 12 was amended to replace trademarks with generic terminology; and claim 17 was amended to indicate that pharmaceutical compositions must be administered to patients in an effective amount.

In light of the above considerations, Applicants believe that all of the examiner's rejections under 35 U.S.C. § 112, second paragraph have been overcome. It is therefore respectfully requested that these rejections be withdrawn.

II. Rejection of Claims Under 35 U.S.C. §§ 102 and 103

On pages 3–5 of the Office Action, the Examiner cites several references as a basis for rejecting claims under 35 U.S.C. § 102 or § 103. Applicants respectfully traverse each of the rejections with respect to the claims as amended herein.

A. Distinguishing Features of the Claimed Composition

There are several elements that are recited in amended claim 1 that may be used to distinguish Applicants' composition from those disclosed in the prior art. First, the claimed composition is an emulsion or microemulsion in which oil is dispersed in water. Second, the local anaesthetic is added to the composition in oil form and, as a result, it distributes between oil and water phases. Thus, page 6 of the specification, lines 15–21 state:

The pharmaceutical composition according to the present invention is preferably a microemulsion. By microemulsion we mean a formulation that consists of water, oil, and amphiphile(s) which constitute a single optically isotropic and thermodynamically stable liquid solution (I. Danielsson and B. Lindman, *Colloids Surf.* 3:391 (1981)). This provides a suitable amount of the local anaesthetic in the oil phase, which in turn confers a fast onset of action. No separate oil needs to be added to the composition, since the oil is already present by the active component(s) as such.

Finally, compositions must contain at least one surfactant with thermoreversible gelling properties and the final composition itself must have such properties.

Thus, the three main criteria that can be used in distinguishing the present pharmaceutical composition from similar compositions described in the art are: (a) local anaesthetics in oil form; (b) a composition in the form of an oil in water emulsion or microemulsion; and (c) a composition with thermoreversible gelling properties that result from the presence of a surfactant with such properties. It is Applicant's contention that none of the references cited by the examiner disclose, or reasonably suggest, a composition with all of these elements. Moreover, by extension, the methods by which the claimed compositions are made and used are also neither disclosed nor suggested.

B. Rejection Based Upon EP 241,178 and U.S. 4,780,320

On page 4 of the Office Action, claims 1-6, 8-12, and 17-18 are rejected based upon EP 241,178 and U.S. 4,780,320. It is not entirely clear whether the examiner intended for these references to be considered separately or in combination. However, in either case, Applicants believe that the references cannot render the present claims obvious.

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The '178 application discloses pharmaceutical compositions containing two polymers, one water-soluble and the other insoluble. The insoluble polymer is dispersed in the water-soluble polymer to form a two-phase system. However, apart from the fact that the reference discloses a composition that can be used for delivering local anaesthetics, none of the main characteristics of the claimed compositions are present. The reference does not disclose an oil-in-water emulsion or a preparation with a viscosity that changes after introduction onto a mucous membrane of a patient.

The second reference cited in the Office Action, i.e., the '320 patent, discloses a drug delivery system that can be placed in the periodontal pocket. However, the composition does not contain an oil/water emulsion. Instead, it consists of microparticles or microcapsules dispersed within a polymer. Microparticles and microcapsules are small beads characterized by the presence of a distinct membrane separating the interior of the bead from the surrounding medium. There is no suggestion to use oil in the place of the microcapsules or microparticles. Even if the teachings of this patent are combined with those in the '178 published application,

one would not arrive at the inventions claimed by the present Applicants in that no suggestion exists for the creation of the presently claimed emulsions.

In light of the above considerations, Applicants submit that the '320 and '178 references, either alone or in combination, do not render the present invention obvious. It is therefore respectfully requested that the examiner's rejection of claims based upon these references be withdrawn. If the examiner chooses to maintain the present rejection, it is respectfully requested that the specific portions of the references disclosing each of the elements in Applicants' claimed compositions be set forth or that an explanation be given as to why the substitution of a missing element would be obvious.

C. Rejection of Claim 1 Based Upon CA 123:152960

On page 4 of the Office Action, the examiner rejects claim 1 as being anticipated by CA 123:152960. The abstract discloses preparations containing local anaesthetics, water-soluble polymers, and pigments. The most obvious element that's lacking from claim 1 as amended herein is the presence of a surfactant with thermoreversible gelling properties. The examiner appears to have recognized the absence of this element in that claim 8 was not included as part of the rejection. Since the absence of a single element in a reference is sufficient to preclude it from being anticipatory, it is respectfully submitted that the '960 abstract cannot be used to maintain a rejection of amended claim 1 under 35 U.S.C. § 102(a). Applicants therefore respectfully request that the examiner's rejection based upon this reference be withdrawn.

D. Rejection of Claims Based Upon CA 105:11993

The examiner rejects claims 1, 5-6, and 10 under 35 U.S.C. § 102(b) as being anticipated by CA 105:11993. This abstract discloses an oil/water emulsion containing a eutectic mixture of lidocaine and prilocaine. However, there is nothing to suggest the presence of either a surfactant or finalized composition with thermoreversible gelling properties that lead to an increase in viscosity upon insertion of compositions into a periodontal pocket. Moreover, it appears from the disclosure that compositions are intended for use on skin and not on mucosal

surfaces such as those of the oral cavity. Thus, no motivation or suggestion exists for modifying the disclosed composition so that its viscosity changes in the manner claimed.

In light of the above considerations, it is submitted that the abstract cited by the examiner is lacking in an essential element of the claimed composition. As such, the abstract cannot serve as a basis for rejecting claims on novelty grounds and the withdrawal of the examiner's rejection is therefore respectfully requested.

E. Rejection of Claims Based Upon WPIDS AN 94/351141

On page 4 of the Office Action, the examiner rejects claim 1 based upon WPIDS AN 94/351141. This abstract discloses local anaesthetic compositions containing essential oils. However, it does not suggest that compositions should be used internally, and, as with the abstracts discussed above, there is no suggestion that surfactants in the compositions should have thermoreversible gelling properties. Similarly, there is no suggestion that the finalized composition be formulated in such a way as to become more viscous when applied to a mucosal surface such as those of the oral cavity. This deficiency appears to have been recognized by the examiner in that claim 8 was not included in the rejection.

In light of the above considerations, Applicants submit that the rejection based upon the '141 abstract has been overcome in the amended claim and it is respectfully requested that this rejection be withdrawn.

F. Rejection of Claims Based Upon U.S. 5,635,540

The examiner rejects claims 1, 3-6, 9-11, and 18 under 35 U.S.C. § 102(e) based upon U.S. 5,635,540. In response, Applicants submit that the reference does not disclose an emulsion, microemulsion, or thermoreversible gel. Instead, it discloses a cream that is applied topically to the skin. In contrast, the claimed composition is directed to a liquid that forms a gel upon contact with a patient's mucous membrane. The absence of, at least, a surfactant with thermoreversible gelling properties appears to have been recognized by the examiner in that claim 8 was not included in the rejection.

In light of the above considerations, Applicants respectfully submit that the examiner's rejection of claims based upon the '540 patent does not anticipate or render obvious the compositions of the amended claims. Applicants therefore respectfully request that this rejection be withdrawn.

G. Rejection of Claims Based Upon EP 455,396

On page 4 of the Office Action, the examiner rejects claims 1-4, 8-12, and 17-18 under 35 U.S.C. § 103 as being unpatentable over EP 455,396. The examiner appears to believe that the only element missing is the presence of an agent to mask the taste of preparations. However, it is Applicants' position that the reference also fails to disclose an oil/water emulsion or microemulsion. The examiner has done nothing to indicate what would suggest the alteration of the disclosed compositions to encompass an oil/water emulsion. It is therefore submitted that the cited reference does not render claims obvious. It is therefore respectfully requested that the examiner's rejection based upon this reference be withdrawn.

G. Rejection of Claims Based Upon U.S. 5,589,180

On page 5 of the Office Action, the examiner rejects claims 1 and 3-4 under 35 U.S.C. § 103 based upon U.S. 5,589,180. However, the reference does not disclose an oil-in-water emulsion or microemulsion. Also, there does not appear to be any suggestion to use thermoreversible compositions since the formulations described do not appear to be designed for insertion into a body cavity.

In light of the above considerations, Applicants respectfully submit that a *prima facie* case of obviousness for the amended claims has not been established. It is therefore respectfully requested that the rejection of claims based upon the '180 patent be withdrawn.

H. Rejection of Claims Based Upon U.S. 5,612,052

The examiner rejects claims 1, 8-10, and 17 under 35 U.S.C. § 103 as being unpatentable over U.S. 5,612,052. Applicants have examined this reference and respectfully submit that it does not disclose an emulsion or microemulsion of oil, water, and local anaesthetic. It also does not

include the presence of a thermoreversible surfactant. Thus, major elements of the claims as amended are missing in the disclosed reference and the examiner has not provided any basis for concluding that a suggestion might exist to incorporate these elements into the disclosure. Also, it should be pointed out that the reference was published after Applicants' filing date, and the basis for rejecting claims under 35 U.S.C. § 102(a) is not at all apparent in the Office Action. If the examiner chooses to maintain the present rejection based upon '052, it is respectfully requested that this matter be clarified. It is therefore submitted that the present rejection of claims cannot be sustained, and it is requested that the rejection under 35 U.S.C. § 103 be withdrawn.

Conclusion

Applicants submit that all of the rejections made by the examiner under 35 U.S.C. §§ 112, second paragraph, 102, and 103 have been overcome by the amendments and remarks made herein. It is therefore respectfully requested that these rejections be withdrawn and that the presently pending claims be allowed.

If, in the opinion of the examiner, a phone call may help to expedite prosecution of the above-captioned application, the examiner is invited to call Applicants' undersigned attorney at (202) 639-6585.

Respectfully submitted,

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